COA 43252-8-II

No. 86224-9

SUPREME COURT
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN

Appellants,

v.

CITY OF PORT ANGELES and CITY OF FORKS

Respondents,

REPLY BRIEF OF RESPONDENTS/CO-APPELLANTS CITY OF PORT ANGELES AND CITY OF FORKS

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1. INTRODUCTION

Petitioners make the absurd and completely meritless claim that the fluoridated drinking water furnished by the Cities, and the Cities' fluoridation additives, are "legend drugs" (requiring a prescription) which may be "seized" as illegally-dispensed prescription drugs under RCW 69.41.060. Fluoridated drinking water and the additives used by the Cities are expressly allowed and comprehensively regulated by the Washington Board of Health and Department of Health.

Petitioners' claim is not grounded in any competent facts or supported by any rational argument based on the law or the facts. It is also directly contradicted by this Court's recent decision in *City of Port Angeles v. Our Water–Our Choice*, 170 Wn.2d 1, 259 P.3d 598 (2010).

The Cities should be awarded their costs and attorneys' fees for having to respond to Petitioners' lawsuit, which is frivolous, advanced without reasonable cause, and violates CR 11. The Court should also grant the Cities' motion for costs and attorneys' fees pursuant to RAP 18.9(a) for having to respond to Petitioners' frivolous appeal of the trial court's dismissal of their Complaint.

2. SUMMARY OF ARGUMENT

The trial court correctly dismissed Petitioners' frivolous claim, noting that Petitioners' remedy was with the Legislature, not the courts.

VRP at 40 (lines 4 – 5). The trial court abused its discretion, however, when it applied the incorrect legal standard and failed to award the Cities their costs and attorneys' fees under RCW 4.84.185 and CR 11. The trial court denied the Cities' request for costs solely because it felt the Petitioners were arguing for a good faith change in the law. VRP at 40 (lines1 – 4). The correct legal standard under RCW 4.84.185 is not "good faith," but whether the claims are supported by rational argument based on the law and facts. The correct legal standard under CR 11 is whether the claim is well grounded in fact **or** whether the claim is supported by a good faith argument for extension of the law. Petitioners make no argument that the trial court applied the correct legal standard. Under the correct standard, Petitioners' claim that the Cities' fluoridated drinking water and fluoridation additives are unlawfully dispensed "legend drugs" is frivolous and violates CR11.[1]

In order to be classified as a "legend drug" under Washington law, a product must both be designated as a prescription drug under federal law and be listed in the 2009 *Drug Topics Red Book*. WAC 246-883-020(2).

[1] The Cities fulfilled their obligation under CR 11 by informing Petitioners' counsel in writing that the Cities would seek sanctions under CR 11 if Petitioners' claim was not withdrawn.

With respect to the first prong of that Board of Pharmacy definition, Petitioners cannot point to a single instance where the federal Food and Drug Administration ("FDA") has treated fluoridated drinking water, or bulk fluoridation additives, as federal prescription drugs. FDA has never regulated drinking water as a drug – much less a prescription drug. 44 FR 42775. After passage of the Safe Drinking Water Act, the FDA determined jointly with the Environmental Protection Agency ("EPA") that the FDA has no jurisdiction to regulate public drinking water or drinking water additives. 44 FR 42775 – 42778 (Memorandum of Understanding 225-79-2001 – the "1979 MOU"). That MOU is still in force.[2] Every court to consider the issue agrees that the FDA does **not** regulate public drinking water or drinking water additives. *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1); *Coshow v. City of Escondido*, 132 Cal. App. 4th 687, 713 (2005). Faced with these uncontested facts and clear authority, Petitioners' argument that fluoridated public drinking water is a designated federal prescription drug is baseless, irrational, and certainly not well grounded in fact.

[2] MOU 225-75-2001 is among the *current* FDA MOUs that are recognized as being in full force and effect by the FDA on the FDA's website: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm

Petitioners' only argument in their Reply completely misrepresents the law to this Court and fails to cite controlling authority. Petitioners argue that Congress somehow designated the Cities' drinking water as a prescription drug under federal law, and that the FDA is "**not responsible for the designation of drugs**."[3] But Congress did not include a single word about fluoride or drinking water in the Federal Food Drug and Cosmetics Act ("FFDCA").[4] In fact, Congress delegated regulation of public drinking water to the EPA in the Safe Drinking Water Act.[5]

And Petitioners ignore contrary and controlling authority from the United States Supreme Court and the Ninth Circuit holding that the FDA has authority to determine the coverage of the FFDCA and to determine whether a product is a "drug" or "food" or "cosmetic" for purposes of federal law.[6]

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[3] Reply Brief at 2 (emphasis added).

[4] 21 U.S.C. §301 *et seq.* In fact, Congress delegated regulation of public drinking water to the EPA in the Safe Drinking Water Act. 42 U.S.C. § 300f *et seq.*

[5] 42 U.S.C. § 300f *et seq.*

[6] *E.g., Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 640, 643-644, 93 S.Ct. 2469 (FDA has authority "to determine in its own proceedings the coverage of the Act [the FFDCA] it administers); *Biotics Research Corp., v. Heckler*, 710 F.2d 1375, 1376-1377 (9th Cir. 1982) (FDA has authority and primary jurisdiction to determine the "status of a product" and whether a product was a "food" or a "drug" under the Federal Food Drug and Cosmetics Act).

Petitioners' attempt to meet the second prong of the controlling Board of Pharmacy regulation is not grounded in any fact. Petitioners admit that neither fluoridated public drinking water nor the actual additives used by the Cities are listed in the 2009 *Drug Topics Red Book.*[7] Petitioners *believe* that fluoridated drinking water and drinking water additives *should* be listed in the 2009 *Drug Topics Red Book.*[8] But that does not meet the controlling Board of Pharmacy definition of legend drug in WAC 246-883-020(2). Petitioners' only argument is to ask the Court to ignore the Board's definition. There is no rational argument based on the law or facts that the Cities' fluoridated drinking water or their fluoridation additives are actually listed in the 2009 *Drug Topics Red Book.* Because there is no such listing, Petitioners have no claim. Petitioners' arguments to the contrary are frivolous and not grounded in the facts or law.

Petitioners' claim is also directly contradicted by recent authority from this Court. In 2010, this Court held that both state and federal law expressly allow fluoridation of public drinking water. *City of Port*

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[7] Reply at 43 – 45.

[8] The Court should recognize that it is the Board of Pharmacy – not the Cities and not the courts – that has primary jurisdiction over rule-making. Petitioners cannot argue in a lawsuit against the Cities for a change in the administrative rules. That must be addressed to the Board of Pharmacy.

Angeles v. Our Water–Our Choice, 170 Wn.2d 1, 259 P.3d 598 (2010). In *City of Port Angeles,* this Court held that:

- the Washington Board of Health and Department of Health regulations permit public drinking water providers (like the Cities) to adopt water fluoridation programs.[9]

- Under federal law, the EPA regulates public drinking water and additives; and the FDA does not regulate public drinking water or additives.[10]

- The Washington Legislature vested the Department of Health and Board of Health with the authority to regulate public drinking water.[11]

- Those state agencies comprehensively regulate public drinking water systems, including regulation of fluoride in public drinking water.[12]

- Under that controlling Washington law, "**Fluoride is one of the permitted chemicals**" that may be added to public drinking water.[13]

Petitioners evidently *believe* that fluoride should not be a permitted additive to public drinking water. But their arguments at law (as opposed to policy arguments) are not supported by any rational argument based on the law and are not grounded in fact. This Court should protect the Cities' rate payers from having to defend against this continuing series of

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[9] *City of Port Angeles*, 170 Wn.2d at 12.
[10] *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1).
[11] *City of Port Angeles*, 170 Wn.2d at 8; RCW 43.20.050.
[12] *City of Port Angeles*, 170 Wn.2d at 9; Chapter 246-290 WAC.
[13] *City of Port Angeles*, 170 Wn.2d at 9 (emphasis added).

meritless lawsuits and appeals by awarding the Cities their costs and attorneys' fees under RCW 4.84.185, CR 11, and RAP 18.9.

3. ARGUMENT

3.1 The Trial Court Applied the Incorrect Legal Standard and Therefore Abused its Discretion When it Denied the Cities' Costs and Attorneys' Fees.

The trial court's denial of the Cities' request for costs and reasonable attorneys' fees is reviewed for abuse of discretion. *Washington State Physician Ins. Exch. & Ass'n v. Fisons Corp.*, 12w Wn.2d 299, 858 P.2d 1054 (1993). The trial court abuses its discretion if it applies an incorrect legal standard or applies incorrect legal analysis. *Dix v. ICT Group, Inc.*, 160 Wn.2 826, 833, 161 P.3d 1016 (2007); *In re Welfare of B.R.S.H.*, 141 Wn. App. 39, 56, 169 P.3d 40 (2007).

In this case, the Cities requested costs and fees under both RCW 4.84.185 and CR 11. The trial court denied that application based solely on its finding that Petitioners were "acting in good faith and arguing for a good faith change to the law." VRP at 40 (lined 3 – 4). The trial court applied the incorrect legal standard under both RCW 4.84.185 and under CR 11 and, therefore, abused its discretion.

The correct legal standard under RCW 4.84.185 is whether Petitioners' claim is supported by rational argument based on the law and the facts. *Déjà Vu-Everett-Federal Way, Inc. v. City of Federal Way*,

119 Wn.2d 129, 137, 830 P.2d 350 (1992). It is irrelevant whether the Petitioner is acting in "good faith." If the claims are not rationally based on the law and facts, they are frivolous.

The correct legal standard under CR 11 is whether Petitioners' claim is either not well grounded in fact or not warranted by existing law or a good faith argument for the extension of existing law. *MacDonald v. Korum Ford*, 80 Wn. App. 877, 883 – 884, 912 P.2d 1052 (1996). The trial court applied only one of those two independent standards under CR 11– whether Petitioners were arguing in good faith for a change in the law. The trial court ignored the other standard – whether Petitioners' Complaint and other filings were well grounded in fact.

In their Reply, Petitioners merely quote the legal standard under RCW 4.84.185 and CR 11. Petitioners do not make any argument that the trial court used the correct legal standard. Under the correct standards (the frivolous suit standard of RCW 4.84.185 and the "well grounded in fact" standard under CR 11), the Cities should be awarded their costs and attorneys' fees. Even under the standard used by the trial court (the alternate CR 11 standard for claims based on a "good faith argument" for extension of existing law), the trial court should have granted the Cities' motion for terms. Since at least the *City of Port Angeles* case, the

Petitioners have known that the FDA does not regulate public drinking water, and, therefore, fluoridated drinking water cannot possibly be a designated federal prescription drug. If Petitioners had acted in "good faith," they would have petitioned the FDA, as required by law, before bringing any action in court.[14] Instead of seeking relief before the expert agency, Petitioners filed a meritless claim against the Cities. Petitioners want to make a political statement rather than act in good faith.

The Cities have also moved for their costs and fees on this appeal, under RAP 18.9(a). An appeal is frivolous if there are no debatable issues upon which reasonable minds might differ and is so devoid of merit that there was no reasonable possibility of reversal. *Eugster v. City of Spokane*, 139 Wn. App. 21, 34, 156 P.3d 912 (2007). Application of that standard calls for the award of costs and fees on appeal in this matter.

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[14] *Biotics Research Corp.*, 710 F.2d at 1376 – 1377 (FDA has primary jurisdiction to determine whether product is a drug and courts will not hear case until agency has acted); *Estee Lauder*, 727 F. Supp. at 6 – 7 (plaintiff seeking determination that product was a cosmetic, rather than a drug, was required exhaust administrative remedies before the FDA before bringing suit); *see* 21 C.F.R. §§ 10.20, 10.30 and 10.25(a).

3.2 Petitioners' Complaint and this Appeal Are Frivolous – the Claim that the Cities' Fluoridated Drinking Water and Fluoridation Additives Are "Legend Drugs" Is Not Well Grounded in Fact or Supported by any Rational Argument Based on the Law.

Under Chapter 69.41 RCW, legend drugs are those products that may only be dispensed by prescription or may only be used by medical professionals to treat patients.[15] RCW 69.41.020(12). The Legislature expressly delegated to the Washington Board of Pharmacy the authority to identify what is a legend drug for purposes of Chapter 69.41 RCW. RCW 69.41.075.

In response, the Board of Pharmacy has defined "legend drug" for purposes of Chapter 69.41 RCW as follows:

> (1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been **determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act**, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

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[15] The additives used by the Cities to fluoridate their public drinking water are neither dispensed nor used to treat patients. The Cities only distribute drinking water. Accordingly, Petitioners' arguments about the Cities' drinking water additives are completely irrelevant. Those additives are also expressly allowed and regulated by the Board of Health and Department of Health. WAC 246-290-220; WAC 246-290-460.

> (2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law **and** are listed as such in the 2009 edition of the *Drug Topics Red Book*. . . .

WAC 246-883-020(1) & (2) (emphasis added).

Just like the federal courts, the Board of Pharmacy recognizes in the above-quoted regulation that the FDA is the agency that designates whether a product is a prescription drug under federal law.[16] The Board then adopts a two-part definition of legend drugs under Washington law "for purposes of chapter 69.41 RCW": (a) the product must be designated as a legend drug under federal law; and (b) the product must be listed as a legend drug in the 2009 *Drug Topics Red Book*.

Petitioners request the Court to ignore this controlling definition from the Board of Pharmacy, even though Petitioners cited to that same definition in their Complaint.[17] Instead, Petitioners want the Court to consider only the general definition from RCW 69.41.020(12), which mentions drugs designated as prescription drugs under federal law, and does not mention the 2009 *Drug Topics Red Book*. Petitioners' argument

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[16] *Bentex Pharmaceuticals*, 412 U.S. at 643-644; *Biotics Research Corp.*, 710 F.2d at 1376-1377.

[17] Complaint at 3 (¶6) and 4 (¶8). In fact, the Complaint fairly read admits that a legend drug must be listed in the 2009 *Drug Topics Red Book*. Complaint at 4 (¶8 and ¶10).

has no merit, and the Board of Pharmacy definition of "legend drug" controls.

No matter which definition the Court uses, however, there is no law or fact supporting Petitioners' frivolous claim that fluoridated drinking water or fluoridation additives either have been designated as prescription drugs under federal law or are listed in the 2009 a *Drug Topics Red Book* (as required by the Board of Pharmacy).

3.2.1 Fluoridated Public Drinking Water and Drinking Water Additives Are Not Designated Prescription Drugs under Federal Law.

The FFDCA is the federal law regulating the manufacture, use and sale of drugs – as well as foods and cosmetics. 21 U.S.C. § 301 *et seq.* In the FFDCA, Congress included broad, general definitions of the terms "drug," "food," "food additive," "cosmetic," "device," and "prescription drug." 21 U.S.C. § 301(g)(1); 21 U.S.C. § 301(f); 21 U.S.C. § 301(s); 21 U.S.C. § 301(i) 21 U.S.C. § 301(h); and 21 U.S.C. § 353(b)(1). The FDA was authorized to implement and enforce the FFDCA, including those definitions. 21 U.S.C. §§ 371 through 377.

There is **no** mention anywhere in the FFDCA of fluoridated public drinking water or fluoridation additives. And there is **no** designation by Congress of fluoridated public drinking water or any fluoridation additive

as a drug in the FFDCA.[18] Rather, it is the expert federal agency – the FDA – that determines and designates whether a substance or product is a drug, or a food or a cosmetic regulated under the FFDCA. Every court to consider this question, including the United States Supreme Court, agrees that the FDA has authority to determine its jurisdiction under the FFDCA and to designate whether a product is a "drug" under federal law. *E.g., Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 626-627, 93 S.Ct. 2469 (1973) (FDA has "primary jurisdiction" to determine if a product is a drug or a new drug under the FFDCA); *Bentex Pharmaceuticals,* 412 U.S. at 643-644 (FDA has authority to determine the coverage of the FFDCA); *Dietary Supplements Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563-564 (9th Cir. 1992) (FDA had primary jurisdiction to determine whether "Co-enzyme Q10" was a dietary supplement or a food additive under the FFDCA); *Biotics Research Corp.*, 710 F.2d at 1376 (FDA had primary jurisdiction to determine whether the product Interferon was a food or a drug under the FFDCA); *Estee Lauder, Inc., v. U.S. Food & Drug Administration*, 727 F. Supp. 1, 6 (D.D.C.

[18] In fact, Congress authorized the EPA, not the FDA, to regulate public drinking water when it passed the Safe Drinking Water Act. 42 U.S.C. 300g-1.

1989) (FDA had jurisdiction to determine whether plaintiff's skin cream product was a cosmetic or a drug under the FFDCA).

Moreover, because FDA has primary jurisdiction, the courts will not rule on whether a product is a drug under the FFDCA until plaintiffs have exhausted administrative remedies before the FDA and the FDA has completed its administrative process. *E.g., Dietary Supplemental Coalition*, 978 F.2d at 563 – 564; *Biotics Research Corp.*, 710 F.2d at 1377; *Estee Lauder*, 727 F. Supp. at 6 – 7. Because the U. S. Supreme Court and 9th Circuit hold that the FDA has authority to determine its jurisdiction and to designate whether a product is a drug, Petitioners' bald-faced claim in their Reply (that the FDA is "not responsible for the designation of drugs"[19]) is beyond meritless. It is a misrepresentation of controlling law to this Court, and should be sanctioned through enforcement of CR 11 and RAP 18.9(a).

The FDA has passed extensive regulations implementing the FFDCA. 21 C.F.R. Parts 1 through 1040. **None** of those regulations regulate public drinking water or fluoridation additives to public drinking water.[20]

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[19] Reply Brief at 2.

[20] The FDA does regulate other type of products containing fluoride. For example, the FDA sets limits on fluoride in bottled water. 21 C.F.R.

In fact, the FDA has exercised its authority to determine its jurisdiction and, in coordination with the EPA, the FDA has determined that the FDA has **no jurisdiction** to regulate public drinking water. 42 FR 42775 – 42778 (the "1979 MOU" – attached as App. A). In the 1979 MOU, the FDA and EPA jointly determined that Congress's passage of the Safe Drinking Water Act ("SDWA") in 1974 granted the EPA exclusive jurisdiction to regulate public drinking water systems. 42 U.S.C. 300g-1; *see generally* 42 U.S.C. 300f *et seq.*

Prior to the SDWA, the FDA had regulated public drinking water as a food (not as a drug), similarly to how the FDA regulates fluoridated bottled water currently. 44 FR 42775; 21 C.F.R. 165.110. In the 1979 MOU, the FDA and EPA determined that:

- the "express intent of the [Safe Drinking Water] Act was to give EPA exclusive control over public drinking water supplies,"
- FDA's jurisdiction over public drinking water was repealed, and
- "the EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives to such water."

44 FR 42776 (emphasis added). This Court held in the *City of Port Angeles* opinion that the FDA has no jurisdiction over public drinking

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§ 165.110, and the FDA regulates fluoridated toothpastes and over-the counter fluoride rinses. 21 C.F.R. Part 355. But the FDA does **not** regulate fluoride (or anything else) in public drinking water.

water. *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1); *see also Coshow v. City of Escondido*, 132 Cal. App. 4th at 713 (2005) ("The FDA's authority over food, drugs and cosmetics, including its regulation of fluoride in various products, does not extend to public supplies of drinking water.").

Petitioners' argument that the 1979 MOU was rescinded by EPA in 1988 is not based on any rational argument and, more directly, seeks to mislead the Court. In 1988, EPA terminated an advisory program providing technical assistance to drinking water utilities and initiated a program with the National Science Program ("NSF") to develop private sector additive standards.[21] The notice merely advised of EPA's decision. The 1988 notice not only had no impact on the 1979 MOU, but the 1988 notice actually reaffirmed the 1979 MOU. 53 FR 25586 at p. 2 (see App. D to Cities' Response Brief). Petitioners' assertion to the contrary is demonstrably false.

Since 1988, both the EPA and FDA have repeatedly affirmed the continuing validity and authority of the 1979 MOU. In a formal rulemaking in 1993, five years after EPA's notice, the FDA stated:

> To avoid any misunderstanding, FDA notes that it does not have authority to set standards for public drinking water.

[21] The Washington Board of Health has adopted the NSF additive standards at WAC 246-290-220.

58 FR 378 (January 5, 1993) (see App. E to Cities' Response Brief). In a formal legal and policy interpretation in 1998, the FDA and EPA both affirmed that "Under the [1979] MOU, EPA has regulatory responsibility for substances added to a public drinking water system." 63 FR 54532 at 9 – 10 (October 9, 1998) (see App. F to Cities' Response Brief). The FDA website still lists the 1979 MOU as one of the FDA MOUs that is still in full force and effect.[22]

There is no rational argument based on the law or well grounded in fact that the Cities' fluoridated public drinking water, and its fluoridation additives, are designated as federal prescription drugs. Congress did not even mention public drinking water in the FFDCA. And Congress gave exclusive jurisdiction to the EPA to regulate public drinking water systems in the SDWA. The FDA itself, which is the federal agency with primary jurisdiction and authority to determine whether a substance is a prescription drug, simply does not regulate public drinking water or drinking water additives.

Petitioners' only claim of factual "evidence" to the contrary is based on a single sentence, quoted out of context, in an informal letter

[22] http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm

written by an FDA staffer to a congressperson.[23] That letter correctly states that FDA does regulate some fluoride products, but also correctly states (in the same paragraph) that "**As you know, the Environmental Protection Agency regulates fluoride in the water supply**." CP at 352 (emphasis added). Far from being evidence of FDA regulation, this letter reinforces that fact that the FDA does **not** regulate fluoride in public drinking water.

Petitioners' strained argument that EPA does not regulate drinking water additives is both irrelevant and without merit.[24] Petitioners argue that because EPA sets "maximum contaminant levels," the SDWA is merely a cleanup statute and not related to drinking water additives. This argument illustrates the tortured and irrational arguments Petitioners make to this Court.

Petitioners' argument regarding EPA regulation is totally irrelevant as to whether the FDA has actually designated fluoridated public drinking water or drinking water additives as a prescription drug. With respect to the EPA, however, a "contaminant" is defined in the SDWA as "**any**

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[23] Such correspondence is not a formal FDA ruling, such as the 1979 MOU or the 1993 rulemaking affirming the MOU, and therefore has no legal status.

[24] Note that the Washington Board of Health does specify exactly what additives may be used to treat public drinking water. WAC 246-290-220.

physical, chemical, biological, or radiological substance or matter in water" – irrespective of the source. 42 U.S.C. § 300f(12) (emphasis added). The EPA controls additives (and non-added, naturally-occurring substances) in public drinking water by setting maximum contaminant levels for any substance ("contaminant") that EPA determines may have an adverse health effect. 42 U.S.C. § 300f(1). Irrespective of how EPA controls additives in public drinking water, however, that fact is irrelevant to whether public drinking water or additives to drinking water have been designated as a federal prescription drug by the FDA. They clearly have not been so designated, and Petitioners have known this since at least the issuance of this Court's decision in *City of Port Angeles*.

3.2.2 Fluoridated Public Drinking Water and Drinking Water Additives Are Not Listed in the 2009 *Drug Topics Red Book*.

To be a "legend drug" under Washington law, a product must be designated as a prescription drug under federal law and be listed in the 2009 *Drug Topics Red Book*. WAC 246-883-020(2). As discussed above, there is no argument based on the facts or rationally based on the law that fluoridated public drinking water and drinking water additives are designated federal prescription drugs. There is also no rational argument

that fluoridated public drinking water or the Cities' fluoridation additives are listed in the 2009 *Drug Topics Red Book.*

Petitioners have never argued that public drinking water is listed in the 2009 *Drug Topics Red Book. See* CP at 366 – 374; CR 35 – 44. Rather, Petitioners simply ask the Court to ignore the controlling Board of Pharmacy regulation. But the Board of Pharmacy has express authority delegated by the Legislature to define "legend drug" for purposes of Chapter 69.41 RCW. RCW 69.41.075. The Board requires a legend drug to be listed in the 2009 *Drug Topics Red Book.* This Court must respect that Legislative delegation, and apply the Board of Pharmacy regulation.

The additives used by the Cities are also not listed in the 2009 *Drug Topics Red Book.*[25] The City of Port Angeles uses bulk hydrofluorosilicic acid to treat its public drinking water supply. Petitioners admit that no form of hydrofluorosilicic acid is listed in the 2009 *Drug Topics Red Book.*[26] Petitioners' only argument is that

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[25] The bulk additives used by the Cities would not even meet the threshold definition of "legend drug" in Chapter RCW 69.41, which defines a legend drug as a product that is "dispensed" or used itself to treat patients. RCW 69.41.020(12). The Cities only "dispense" drinking water. The Cities use the additives only to treat that public drinking water to achieve the concentration of fluoride ion specified by the Board of Health. WAC 246-290-460.

[26] Reply at 45.

hydrofluorosilicic acid *should* be listed because it is a common fluoridation product. Using that "logic," this Court would find every tube of fluoride toothpaste on the shelves of the local grocery to be a legend drug subject to seizure. Petitioners' argument is irrational and meritless.

The City of Forks uses bulk sodium fluoride to treat its public drinking water supply (delivered in bulk shipments – pallets of 50-pound bags). Again, Petitioners admit that 50-pound bags of sodium fluoride for treating drinking water are not listed in the 2009 *Drug Topics Red Book.*[27] Petitioners are reduced to arguing that these bulk additives *should* be considered as adequately listed, because other types of products using sodium fluoride are listed.[28] That provides no basis for a seizure action under RCW 69.41.060. *State v. Keating*, 30 Wn. App. 829, 638 P.2d 624 (1981) (for seizure of ephedrine under RCW 69.41.060, state was required to prove that the ephedrine possessed by defendant was not one of the many forms of ephedrine available without prescription).

If "should be listed" is the standard to be applied, this Court will become the outlet for any party seeking a legislative or administrative

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[27] Reply at 44.

[28] The 2009 *Drug Topics Red Book* lists certain specific compounds of sodium fluoride such as flavored fluoride rinses and topical drops. CP 41 – 44. 50-pound bags of sodium fluoride for treating drinking water are **not** listed.

change. But "should be listed" is not the standard. The well-established rule of law requires more than a policy argument of what a regulation or state *should* require. Courts interpret and apply statutes and regulations as they are enacted by legislative bodies or adopted by administrative agencies – not as how they *should* have been adopted. Petitioners knew that the fluoridated public drinking water and the Cities' fluoridation additives were not listed in the 2009 *Drug Topics Red Book.* Petitioners also knew, since at least the *City of Port Angeles* case, that the FDA did not regulate public drinking water systems. Rather than address their complaints to the expert agencies that can change regulations,[29] Petitioners brought this meritless lawsuit against the Cities.

In sum, there are no rational legal arguments and no facts supporting Petitioners' frivolous claim that the Cities' fluoridated drinking water and fluoridation additives are listed in the 2009 *Drug Topics Red Book* – as required by the Board of Pharmacy. Similarly, there are no rational arguments or facts supporting Petitioners' claim that the Cities' fluoridated drinking water and fluoridation additives are designated

[29] An interested person may petition the FDA to amend or revoke any regulation or order or take any other form of administrative action. 21 C.F.R. §10.25(a). Under Washington law, an interested person may petition the Board of Pharmacy to adopt or amend a rule. RCW 34.05.330.

federal prescription drugs. The FDA designates federal prescription drugs. The FDA has authority to determine its jurisdiction, and the FDA has determined (with EPA) that the FDA does not have jurisdiction to regulate public drinking water systems. Petitioners may believe FDA should exercise its jurisdiction differently, but it is beyond any rational argument that the FDA does not regulate fluoride (or any other substance) in public drinking water systems.

As noted by the trial court, Petitioners' argument is with the Legislature (or with the FDA). VRP at 39 – 40. Instead of bringing their concerns to those proper forums, Petitioners have brought this absolutely meritless lawsuit against the Cities, with the preposterous claim that fluoridated public drinking water and the fluoridation additives expressly approved by the Board of Health and Department of Health are "legend drugs" that should be seized pursuant to court order.

Petitioners do not even attempt to argue that the trial court used the correct standard when ruling on the Cities' request for costs and attorneys' fees under RCW 4.84.185 and CR 11. Based on the correct standard, this Court should award the Cities' costs and attorneys' fees on both those grounds. As discussed in detail above, Petitioners' claim is frivolous under RCW 4.84.185, because it is not supported by any rational argument

based on the law or facts. Petitioners and Petitioners' attorney also violated CR 11 because their claim that fluoridated drinking water and fluoridation additives are legend drugs is not well grounded in fact.

Even under the alternate standard in CR 11 ("good faith argument" for the extension of existing law) used by the trial court, the Cities should have been awarded terms. Petitioners knew, after the *City of Port Angeles* decision, that the FDA did not regulate public drinking water and additives, therefore, were not a federal prescription drugs. Petitioners also knew that fluoridated public drinking water and the Cities' fluoridation additives were not listed in the 2009 *Drug Topics Red Book*. Rather than address their concerns and complaints to those expert agencies, as required because they have primary jurisdiction,[30] Petitioners chose to bring a frivolous lawsuit against the Cities. This deliberate flouting of the proper administrative process is certainly not acting in good faith.

In addition, the Court should grant the Cities' motion for their costs and attorneys' fees under RAP 18.9(a) for having to defend this

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[30] *Biotics Research Corp.*, 710 F.2d at 1376 – 1377 (FDA has primary jurisdiction to determine whether product is a drug and courts will not hear case until agency has acted); *Estee Lauder*, 727 F. Supp. at 6 – 7 (plaintiff seeking determination that product was a cosmetic, rather than a drug, was required exhaust administrative remedies before the FDA before bringing suit).

frivolous appeal. Petitioners have raised no debatable issues in their appeal, and there is no reasonable possibility of reversal of the trial court's decision dismissing their Complaint and denying their Motion to Amend.

4. CONCLUSION

The City of Port Angeles and the City of Forks request the Court to uphold the trial court's dismissal of Petitioners' Complaint; to uphold the trial court's dismissal of Petitioners' Motion to Amend; to overturn the trial court's denial of the Cities' request for costs and attorneys' fees under both RCW 4.84.175 and CR 11, and remand for an award of those costs and fees; and to award the Cities their costs and reasonable attorneys' fees under RAP 18.9(a).

RESPECTFULLY SUBMITTED this 23rd day of March, 2012.

FOSTER PEPPER PLLC

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WILLIAM FLECK, FORKS CITY ATTORNEY

Roger A Pearce for

William "Rod" Fleck, WSBA #23962
Attorney for Respondent City of Forks

APPENDICES

A. MOU 225-79-2001 between the EPA and FDA (July 20, 1979). 44 FR 42775 – 42778.

Federal facilities. Prior to making a final recommendation to the Administrator, U.S. EPA, the Regional Administrator, Region V, is providing opportunity for public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. EPA, Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604, Attention: Permit Branch. Such comments will be made available to the public for inspection and copying. All comments or objections received by August 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and all comments received are on file and may be inspected and copied (@ 20 cents/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of this notice are available upon request from the Enforcement Division of U.S. EPA, Region V, by contacting Dorothy A. Price, Public Notice Clerk (312–353–2105), at the above address.

Dated: July 13, 1979.

John McGuire,

Regional Administrator.

[FR Doc. 79-22872 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Drinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Drinking Water and Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection Agency and Food Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH–550), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: David W. Schnare, Ph.D., Office of Drinking Water (WH–550), Environmental Protection Agency, Washington, D.C. 20460, (202) 755–5643; or Gary Dykstra, Enforcement Policy Staff (HFC–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for bottled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the **Federal Register** of October 3, 1974, (39 FR 35697) stating that future memoranda of understanding, and agreements between FDA and others would be published in the **Federal Register**, the following memorandum of understanding is issued:

Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

I. Purpose

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

(1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

(2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

(3) That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

(4) That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

(5) That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

(6) That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, *inter alia*, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, *inter alia*, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, *inter alia*, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that;

(1) EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) *FDA Legal Authority.* "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(f)). Under Section 402, *inter alia*, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 403, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410

of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

(B). *EPA Legal Authority.* The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, *inter alia*, labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

(1) To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

(2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

(B). FDA's responsibilities are as follows:

(1) To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing;

(2) To provide assistance to EPA to facilitate the transition of responsibilities, including:

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

(c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Dated: June 13, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

Dated: June 22, 1979.

Donald Kennedy,

Administrator, Food and Drug Administration.

Implementation Plan

EPA is concerned that direct and indirect additives may be adding harmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and coagulant aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings. This notice is being published in the **Federal Register** to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a variety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act, EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

hazards should such situations arise. Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to health and the environment as well as authority to limit some or all uses of harmful chemicals. Pesticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Past Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by manufacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

1. *Problem Definition.*—EPA will contract for *in situ* monitoring to determine use patterns and the contribution of trace contaminants to drinking water from:

a. bulk chemicals.

b. generic classes of paints and coatings.

c. pipes and equipment.

d. coagulant aids.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for chemicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be assessed.

2. *Review of Past Advisories.*—The same data base derived from *in situ* monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g., paints, coagulant aides, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. *Future Toxicological Advisories.*—Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, and industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate.

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening sections of this notice.

Dated: July 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management.

Appendix A

Safe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endangerment to the health of persons.

Section 1445—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as are necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—testing of chemical substances and mixtures.

Section 5—pre-manufacture notice required for new chemicals or significant new uses.

Section 6—regulation of hazardous chemical substances and mixtures which pose an unreasonable risk of injury to health or the environment, including restrictions on manufacture, processing, distribution, and use.

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 8—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development. Development of systems for storing, retrieving and disseminating data.

Section 11—inspections and subpenas and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspenstion and cancellation procedures.

[FR Doc. 79-22222 Filed 7-18-79; 8:45 am]

BILLING CODE 6560-01-M

BILLING CODE 4110-03-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A-1a]

FM Broadcasting Applications Accepted for Filing and Notification of Cut-off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was *inadvertently included on the* acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 18678, released on June 25, 1979.

BPH-790108AE (New): Cresson, Pennsylvania, Sherlock-Hart Broadcasting, Inc.
Req.: 94.3 MHz, Channel #232A
ERP: 0.600 kW, HAAT: 600 feet

Accordingly, the application is removed from the acceptance/cutoff list and the August 6, 1979, cutoff date is deleted.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 79-22422 Filed 7-19-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees Involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations Authority.

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretation, and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of business on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER INFORMATION CONTACT: Harold D. Kessler, Deputy Executive Director, 1900 E Street, NW., Washington, D.C. 20424, (202) 632-3920.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1979 (43 FR 36037). Since January 11, 1979, the Authority has conducted its operations under the Federal Service Labor-Management Relations Statute (92 Stat. 1191).

Upon receipt of requests and consideration thereof, the Authority has determined, in accordance with 5 CFR 2410.3(a) (1978) and sections 7105 and 7135(b) of the Statute (92 Stat. 1196, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Government Employees (AFGE) for a statement of policy and guidance concerning whether employees representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses under the official time provisions of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214). Additionally, the National Federation of Federal Employees (NFFE) has requested a major policy statement as to *the application of the official time* provisions of section 7131(a) of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2410.3(a) (1978) and section 7135(b) of the Statute (92 Stat. 1215), as well as section 7105 of the Statute (92 Stat. 1196), that an interpretation of the Statute is warranted on the following:

(1) Whether employees who are on official time under section 7131 of the Statute while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuant to 5 CFR 2410.6 (1978) and section 7135(b) of the Statute (92 Stat. 1215), solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington, D.C., July 13, 1979.

Federal Labor Relations Authority.

Ronald W. Haughton,

Chairman.

Henry B. Frazier III,

Member.

[FR Doc. 79-22449 Filed 7-19-79; 8:45 am]

BILLING CODE 6325-01-M